

## REMARKS

### In the drawings:

Per the Examiner's requirement, Applicant submits formal replacement drawings, which include among other things, clear details of the medial tracking member 40, medial tracking member 110, slot 112, medial tracking member 200, and inward tracking member 230.

### In the specification:

Paragraphs 0017-0023, on lines 10-27 of page 4, are amended to clarify that the present invention is alternately or additionally directed to various combinations of elements, used singly or together. The scope of the invention does not require that all, or even multiple, of the various objects be met to fall there within.

Paragraph 0074, on line 23 of page 12, is amended to correct a typographical error, by eliminating the word "in".

### Claims 1-29

Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of pending claims 1-29, because:

- (1) a *prima facie* case of anticipation has not been made regarding claims 1, 15 or 27; and
- (2) a *prima facie* case of obviousness has not been made regarding claims 1, 15 or 27.

**Neither Labour nor Lehman anticipate the claims because they (1) do not necessarily teach one of the structural limitations recited within claims 1, 15, or 27, and indeed (2) cannot perform this limitation's recited function.**

### Labour

Claims 15-16, 19-21, and 26 stand rejected as being anticipated by United States patent number 4,445,505 ("Labour").

Applicant respectfully requests, however, that the Examiner reconsider and withdraw the rejection of pending claims 15-16, 19-21, and 26 because a *prima facie* case of anticipation has not been made regarding claim 15, from which these claims depend.

Labour does not explicitly teach the following limitations of these claims:

“an inward tracking member that fits operatively over, and provides inward pressure against, the patella;  
wherein the inward tracking member provides a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.”

Thus, during a personal interview on July 13, 2006 the question arose as to whether the structural limitation, “inward tracking member”, and its recited function, *i.e.*, in which it “provides a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove”, were inherent to Labour.

Labour does not inherently teach the structural limitation, “inward tracking member”, or its recited function, *i.e.*, in which it “provides a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove[.]” because these features are not *necessarily* present in Labour. “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. “The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).” *Manuel of Patent Examining Procedure* § 2112, IV, Eight Ed., August 2001, Latest Rev., August 2006 (“M.P.E.P.”) (*emphasis added*). Indeed, based on the teachings in Labour, it is much more likely and probable that Labour does not have an “inward tracking member” and does not “provide[ ] a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.”

Labour’s strap 80 would not be recognized by one having ordinary skill in the art as being an “inward tracking member[.]” First, no matter how tightly Labour’s device is adjusted, the patella is nested and thus protected from inward tracking by the opening 30, *see* Labour, col. 3, lines 3-4 (“relieves pressure against the patella”). Besides, Labour’s strap 80 can be tightened only to a very limited extent. The lengths of hook and loop fabric disclosed in Labour are too short ever to overlap such that strap 80 would inwardly track a patella. Second, strap 80 is too wide to provide inward tracking. It overlaps the top side of opening 30, which nestles the patella within. Third, the fabric used at the time of Labour is too thick for strap 80 to provide inward tracking. The neoprene fabric most likely used as the elasticsized fabric in Labour’s brace is too thick for strap 80 inwardly to track a patella through opening 30. Therefore, because nothing in Labour’s device can possibly inwardly track, it does not possess the structural limitation of an inward tracking member. Moreover, because the device as disclosed in Labour does not have an inward tracking member, and could not have one

without seriously optimizing its various features, it cannot be read as inherently disclosing one. *See* M.P.E.P. § 2112, IV (“The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981).”).

Strap 80 also cannot “provide[] a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove”. Pads 54 and 38 create a nest that coincides with opening 30, in which the patella is protected from inward pressure. *See* Labour, col. 3, lines 35-37 (“It will be noted that the vertical medial edge 54 of pad 36 is curved and lies closely adjacent the edge 32 of the opening 30.”) As a result, opening 30 of Labour creates a raised perimeter around the patella over which strap 80 lays, but does not inwardly impinge upon the patella. Thus, mere prevention of anterior displacement by the strap in Labour cannot inherently rise to the level of meeting the threshold requirement of inward force that increases the surface contact area between the patella-femoral tissue and the trochlear groove (even though these straps are elastic and adjustable), because the circumferential force of a tightened strap compresses only the raised portions that lie around the perimeter of the patella, and not the patella.

To the contrary, relatively less pressure on the patella in the presence of increased circumferential pressure about the remaining entire circumference of the leg at the knee joint, or increased pressure on the pads, which provide support about the sides of the patella, compresses the joint so as to force the patella out and away from the trochlear groove. Evidence of this adverse effect is found by the stated function of strap 80, which is passively to “prevent anterior dislocation”, not to provide inward force to an already misaligned patella. As a result, increased tightening of the adjustable strap 80 would have the opposite effect of inward force so that such action would in effect tend to push the patella outwardly and away from the trochlear groove. *See, i.e.*, Labour, col. 1, line 8 to col. 2, lines 1-2 (“The strap is stretchable and intended to tighten the sleeve about the knee and thereby force the pads [not the patella] firmly in position”); Labour, col. 4, lines 25-48 (“the user may pull the strap as tightly as desired to effectively reduce brace diameter and apply pressure on the pads [not the patella] 36 and 38... ..the strap applies pressure to the pad... to provide a barrier to prevent lateral displacement... ..the strap covers a portion of opening 30 [and] when the strap is pulled tight across the front of the sleeve [no mention of pressure on patella] the strap [passively] prevents anterior displacement of the patella [out] through the opening.”).

Thus, Labour does not inherently teach either an inward tracking member, or an inward tracking member that “provides a compressive force against the patella, thereby increasing the

contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove” because it would not be recognized as necessarily present to one having ordinary skill in the art. “Inherency... may not be established by probabilities or possibilities. “The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’ ” *In re Robertson*, at *id.*

The stated purpose of Labour further illustrates this point. With respect to the patella, Labour is meant only to “include means for preventing lateral displacement of the patella”; it does not have an inward tracking member or provide inward tracking. Labour, col. 1, lines 27-29; *see also*, col. 1, line 7-8. Thus, Labour merely prevents lateral displacement and thereby maintains patella positioning – it does not have an inward tracking member.

As such, Applicant respectfully submits that a *prima facie* case of anticipation does not exist with regard to Labour.

### **Lehman**

Claims 1-8, 14-21, and 26-29 stand rejected as being anticipated by United States patent number 3,804,084 (“Lehman”).

Applicant respectfully requests, however, that the Examiner reconsider and withdraw the rejection of pending claims 1-8, 14-21, and 26-29 because a *prima facie* case of anticipation has not been made regarding claims 1, 15, or 27, from which these claims depend.

Lehman does not explicitly teach the following limitations of these claims:

“an inward tracking member that fits operatively over, and provides inward pressure against, the patella;  
wherein the inward tracking member provides a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.”

Thus, during a personal interview on July 13, 2006 the question arose as to whether the structural limitation, “inward tracking member”, and its recited function, *i.e.*, in which it “provides a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove”, were inherent to Lehman.

Lehman does not inherently teach the structure, “inward tracking member”, or its recited function, *i.e.*, in which it “provides a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove[,]” because these features are not *necessarily* present in Lehman. “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. “The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’ ” *In re Robertson*, 169

F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)” M.P.E.P. § 2112, IV (*emphasis added*). Indeed, based on the teachings in Lehman, it is much more likely and probable that Lehman does not have an “inward tracking member” and does not “provide[ ] a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.”

Lehman’s strip 90 would not be recognized by one having ordinary skill in the art as being an “inward tracking member.” First, no matter how tightly Lehman’s device is adjusted, the patella is nested and thus protected from inward tracking by the opening 36. Besides, Lehman’s strip 90 can be tightened only to a very limited extent. The lengths of hook and loop fabric disclosed in Labour are too short ever to overlap such that strip 90 would inwardly track a patella. Second, strip 90 is too wide to provide inward tracking. It overlaps the top and bottom sides of opening 36, which nestles the patella within. Third, Lehman’s fabric is too thick for strip 90 to provide inward tracking. The “relatively thick” “1/8 to 3/8 inch” fabric used around the patella in Lehman’s brace is too thick for strip 90 inwardly to track a patella through opening 36. *See, e.g.*, col. 3, line 30; col.4, lines 36-37; and col. 5, line 7.. Therefore, because nothing in Lehman’s device can possibly inwardly track, it does not possess the structural limitation of an inward tracking member. Moreover, because the device as disclosed in Lehman does not have an inward tracking member, and could not have one without seriously optimizing its various features, it cannot be read as inherently disclosing one. *See* M.P.E.P. § 2112, IV (“The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981).”).

Strip 90 also cannot “provide[ ] a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove”. Whatever “elastic superimposed support which is adjustable”, *see* Lehman, col. 2, lines 19-20, that is provided by the overlock strip in Lehman – is provided only to tie the stays one to another, not to provide inward tracking. Stay 50 on the lateral side of the patella and stay 52 on the medial side of the patella - along with strips 60 and 62, which overlay “relatively thick” felt edges 20 and 22 on the top and bottom sides of the patella, respectively - provide a superimposed stack of “relatively thick” layers under strip 90. These superimposed layers create a protective nest around the patella that roughly coincides with opening 36, which is formed *also* by layered cut outs 30 and 32. These layers that form opening 36 collectively protect the patella from all inward tracking pressure. As a result, opening 36 of Lehman creates a raised perimeter around the patella over which strip 90 lays, but does not inwardly impinge upon the patella. Thus, any support from the strip in

Lehman cannot rise to the level of meeting the threshold requirement of inward force that increases the surface contact area between the patella-femoral tissue and the trochlear groove (even though these straps are elastic and adjustable), because the circumferential force of a tightened strap compresses only the raised portions that lie around the perimeter of the patella, and not the patella.

To the contrary, relatively less pressure on the patella in the presence of increased circumferential pressure about the remaining entire circumference of the leg at the knee joint, or increased pressure on the stays against the sides of the patella, which provide support about the circular perimeter of the patella – compresses the joint so as to force the patella out and away from the trochlear groove. Evidence of this adverse effect is found by the stated function of strip 90, which is passively to provide “elastic superimposed support”, not to provide inward tracking force to a patella. As a result, increased tightening of the adjustable strip 90 would have the opposite effect of inward force so that such action would in effect tend to push the patella outwardly and away from the trochlear groove. *See* Lehman Fig. 4, wherein strip 90 compresses raised upper and lower strips 60 and 62 and raised stay means 50 and 52, and thereby squeezes the area surrounding the patella. This pressure thus causes outward forces on the knee cap, which makes a resulting inward force that increases patello-femoral contact surface area impossible, or at the very least, highly improbable. *See In re Robertson, at id.* (“Inherency... may not be established by probabilities or possibilities. “The mere fact that a certain thing may result from a given set of circumstances is not sufficient.””).

Thus, Lehman does not inherently teach either an inward tracking member, or an inward tracking member that “provides a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove” because it would not be recognized as necessarily present to one having ordinary skill in the art.

As such, Applicant respectfully submits that a *prima facie* case of anticipation does not exist with regard to Lehman.

### **Labour does not inherently teach the limitations missing from Cawley**

#### **Cawley in view of Labour**

Claims 1-14, 17-18, and 22-25, and 27-29 stand rejected as being obvious over United States patent number 6,551,264 (“Cawley”) in view of Labour.

In view of the above-recited reasoning, however, Applicant respectfully submits that all of these claims are in condition for allowance. In short, Labour does not teach, either inherently or explicitly, an inward tracking member, which is a structural element in all of these claims. Moreover, the art is replete with evidence that teaches away from the use of an inward tracking member. Nearly every, if not every, knee brace in the art - in some way, shape, or form - teaches a protective nest or opening about the wearer’s patella such as the ones found in Labour and Lehman, which prevents inward tracking of the patella.

For all of the forgoing reasons, the Applicant respectfully requests that the examiner withdraw the current rejections and that all of claims 1-29 be allowed.

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Respectfully submitted,



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